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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,928	08/27/2002	Edward Burton	HO-P02428USO	1211

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EXAMINER	
KETTER, JAMES S	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,928	BURTON ET AL.	
	Examiner	Art Unit	
	James S. Ketter	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-70 and 77-91* is/are pending in the application.

4a) Of the above claim(s) *55,57,60 and 61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53,54,56,58-70 and 77-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/4/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election without traverse of Group I in the reply filed on 30 January 2006 is acknowledged. Applicant's further election with traverse of SEQ ID NO:1 and SEQ ID NO:2 (nucleic and amino acid sequences, respectively) in the reply is acknowledged. The traversal is on the ground(s) that searching more than one sequence would not be a burden, and the restriction requirement is therefore unfair. This is not found persuasive because the human and mouse genes are patentably distinct, and are sufficiently different that separate searches would be required. Two such searches would be burdensome in view of the heavy use of sequence search resources at the USPTO.

The requirement is still deemed proper and is therefore made FINAL.

Claims 55, 57, 60 and 61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn **only** to a nonelected invention, there being no allowable generic or linking claim. Furthermore, subject matter with respect to the non-elected sequences where found in a claim with elected subject matter is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 30 January 2006.

Claims 53, 62-70, 77-79 and 82-91 are objected to because of the following informalities: The instant claims encompass subject matter withdrawn from consideration pursuant to 37 CFR 1.142(b). Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 53, 54, 56, 58, 59 and 62-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 5 and 9 of U.S. Patent No. 5,972,609, as follows: instant claims 53, 54, 56, 58-64 over patented claim 4; instant claims

65 and 66 over patented claim 5; and instant claims 67-70 over patented claim 9. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to all that is recited in the respective claims of the patent, i.e., the patented claims fall entirely within the scope of each of the respective instant claims. Both sets of claims are drawn to constructs encompassing the human utrophin promoter region.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53, 62-70, 77-79, 82-88 and 90 are rejected under 35 U.S.C. 102(b) as being anticipated by Tinsley et al. (N, newly cited).

Claim 53 is drawn to an isolated nucleic acid comprising a promoter which comprises a sequence from the promoter of SEQ ID NO:1, free or substantially free of utrophin coding sequence. Claim 62 is drawn to a nucleic acid construct of, among others, claim 53, operably linked to a heterologous sequence. Claim 63 is drawn to a nucleic acid construct of, among others, claim 53, operably linked to a coding sequence, more narrowly specified as a reporter

molecule in claim 64. Claims 65 and 66 are drawn to host cells comprising the nucleic acids of claims 63 and 64, respectively. Claim 67 is drawn to a method of culturing a host cell of claim 65 to express the polypeptide. Claims 68-70 more narrowly claim that the coding sequence encodes a reporter molecule, or that the method encompasses detection of transcription or of expression of the polypeptide, respectively. Claim 77 is drawn to a nucleic acid which comprises a nucleic acid encoding the amino acid sequence of SEQ ID NO:2. Claim 78 is drawn to a nucleic acid which comprises a nucleic acid encoding a polypeptide which is one of the recited variants of the amino acid sequence of Figure 1, wherein it has at least 60% homology to the amino acid of Figure 1 or 2. Claim 79 is drawn to a nucleic acid which comprises a nucleic acid encoding a polypeptide which is one of the recited variants of the amino acid sequence of Figure 1, wherein it hybridizes with the nucleic acid encoding said polypeptide under stringent conditions. Claim 82 is drawn to a nucleic acid of one of claims 77-81 in a vector. Claim 83 is drawn to a nucleic acid of one of claims 77-81 in an expression vector. Claim 84 is drawn to a host cell comprising the vector of claim 83. Claims 85-88 and 90 are drawn to methods of introducing the nucleic acids of 77-81 into a cell, wherein the vector is an expression vector, specifically in vitro, including causing or allowing expression in the cell, and further wherein the expression product is isolated, respectively.

Tinsley et al. teaches, generally, and with particularity at Figure 1, a clone of the promoter region of human utrophin. Clone 4X23E3, as noted at page 20, last full paragraph, and the paragraph bridging pages 20 and 21, comprises the utrophin promoter. At page 21, from "Reporter Gene Expression" through page 22, line 12, teaches attachment of the utrophin

promoter to a reporter gene (luciferase), introduction into cells, expression of the reporter from a vector, isolation of the enzyme and its subsequent detection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 54, 56, 58, 59, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tinsley et al. (N).

Claim 54 is drawn to an isolated nucleic acid consisting essentially of a promoter which comprises the nucleotide sequence upstream of position 1440 of Figure 1. Claims 55-57 are similar, with different nucleotide positions recited; however, the "comprising" language causes these four claims to read upon the entire promoter. Claim 58, similarly, would read upon the entire promoter in that it comprises the recited nucleotide. Claim 59-60 are drawn to isolated

nucleic acids which consist essentially of the promoter sequence in Figure 1, or the recited variants which are at least 60% identical, or a recited variant promoter which hybridizes under stringent conditions to the promoter sequence in Figure 1. Claims 80 and 81 are dawn to a nucleotide that comprises the nucleotide which encodes the amino acid sequence in Figure 9, or which comprises the nucleotide sequence in Figure 9.

Tinsley et al. is described above. At Figure 1 thereof, overlapping genomic clones which together cover the entire human utrophin gene, are disclosed. Tinsley et al. differs from the claimed invention in not actually disclosing a full length, continuous clone of human utrophin gene. Such a continuous clone would read upon claims 80 and 81. A clone of the promoter region only would read upon claims 54, 56 and 58-61.

With respect to claims 80 and 81, it would have been obvious to one of ordinary skill in the art to have merely reconstructed the full length clone of human utrophin from the overlapping clones disclosed in Tinsley et al. The motivation to have done so would have been founded in the prior art, in that one of ordinary skill would have recognized that the functional form of the gene is in its naturally contiguous form, and that the clones were derived from the contiguous form originally. With respect to claims 54-61, it would have been obvious to one of ordinary skill in the art to have made a construct containing only the promoter, i.e., 5' upstream (of the transcription start site) of the utrophin gene, particularly in that clone 4X23E3 contains only a small portion of the transcribed region. Motivation to have done so would have been founded in the prior art, particularly in that Tinsley et al. teaches the general location of the promoter, its function, its minimally necessary components, e.g., at the paragraph bridging pages 5 and 6, and the concept of using the promoter to transcribe a heterologous coding region, e.g., at

page 21, from "Reporter Gene Expression" through page 22, line 12. One of ordinary skill in the art would have recognized that the promoter without utrophin coding sequences would have been useful for driving transcription of other genes, as shown in Tinsley et al., i.e., logically one would not have wanted to carry over sequences from the "wrong" gene into the desired expression construct.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59, 62-70, 78, 79 and 82-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Each of the instant claims reads to some extent upon a nucleic acid which has either: at least 60% homology; or ability to hybridize under stringent conditions to the recited and disclosed promoter sequence or to a nucleic acid which encodes the recited and disclosed amino acid sequence. 1) With respect to the promoter sequence, 60% identity also means 40% mismatch or difference. However, for the promoter to preserve its disclosed function, no elements needed for transcription initiation can be absent. However, neither the specification nor the prior art offers a theory or algorithm of utrophin promoter function which would have permitted one of skill in the art to have known what sequences must be preserved to maintain

utrophin promoter function, i.e., setting forth a sufficiently characterized structure-function relationship for the promoter. With respect to the stringent hybridization language, since a stretch of nucleotides as small as perhaps 20 nucleotides would permit such hybridization, nearly all of the utrophin promoter might be absent from the resulting construct. Again, as set forth above, neither the specification nor the prior art offers a theory or algorithm of utrophin promoter function which would have permitted one of skill in the art to have known what sequences must be preserved to maintain utrophin promoter function. As such, it would not have been apparent to one of skill in the art that Applicants were in possession of the full scope of the claims with respect to promoter sequences. 2) With respect to the amino acid sequence, alteration of one part of a protein might produce an alteration of the conformation of other portions of the protein, deactivating it. Neither the present disclosure nor the prior art offers any theory or of utrophin structure-function which would have permitted one of skill in the art to have known what sequences must be preserved to maintain utrophin function. As such, it would not have been apparent to one of skill in the art that Applicants were in possession of the full scope of the claims with respect to the utrophin amno acid sequence.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53, 62-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53, and therefore claims 62-70 which depend therefrom, recites "substantially free of utrophin coding sequence". However, "substantially" is a relative term, and is defined neither in the specification, nor with any precision in the prior art. As such, the metes and bounds of the claim are unclear.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jsk
April 28, 2006

JAMES KETTER
PRIMARY EXAMINER